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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/938,641	08/27/2001	Achim Marx	211226US0X	2808

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[REDACTED] EXAMINER

KERR, KATHLEEN M

ART UNIT	PAPER NUMBER
1652	S

DATE MAILED: 06/10/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Applicant No.</b>	<b>Applicant(s)</b>	
	09/938,641	MARX ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Kathleen M Kerr	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 08 February 2002.
- 2a) This action is FINAL.      2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-38 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) \_\_\_\_\_ is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) 1-38 are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

- 11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some \* c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

### *Application Status*

1. Claims 1-38 are pending in the instant application.

### *Restriction*

2. Restriction to one of the following inventions is required under 35 U.S.C. § 121:
  - I. Claims 1-6, 10-22, 26-29, drawn to polynucleotides encoding OxyR transcriptional regulator protein and related products and methods, classified in class 435, subclass 69.1.
  - II. Claim 30, drawn to a host cell containing an *E. coli-C. glutamicum* shuttle vector, classified in class 435, subclass 320.1.
  - III. Claims 7-9 and 23-25, drawn to methods of making and/or screening for a polynucleotide encoding OxyR, classified in class 435, subclass 6.
  - IV. Claims 31-37, drawn to methods of making amino acids using OxyR, classified in class 435, subclass 106.
  - V. Claim 38, drawn to the OxyR polypeptide, classified in class 530, subclass 350.
3. The inventions are distinct, each from the other because of the following reasons:

Group II is unrelated to Groups I and III-V. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (M.P.E.P. § 806.04, M.P.E.P. § 808.01). In the instant case, Group II is drawn to a shuttle vector used to move DNA between *E. coli* and *C.*

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*glutamicum*. It is the vector into which the OxyR gene is spliced to be expressed in *E. coli* and/or *C. glutamicum*. While some portions of the vectors pEC-T18mob2 and pT-oxyRexp are common, they are distinct structures used in distinct methods having different functions.

Moreover, the Group II vector is not used in any of the methods of Groups III-V. Thus, Group II is patentably distinct from Groups I and III-V. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Group I is related to Groups III-IV as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case, the product can be used for a materially different process of using the product, such as in the recombinant production of the encoded enzyme. Thus, Group I is patentably distinct from Groups III-IV. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

The DNA of Group I is related to the protein of Group V by virtue of the fact that the DNA encodes the protein. The DNA molecule has utility for the recombinant production of the protein in a host cell. Although the DNA and the protein are related, they are distinct inventions because they are wholly different in structure and function. Moreover, the protein product can be made by other and materially distinct processes, such as purification from a natural source; and the DNA product can be used for processes other than the production of protein, such as

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nucleic acid hybridization assays. Therefore, Groups I and V are patentably distinct. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

The methods of Group III are related to the methods of Group IV by virtue of both methods using the OxyR polynucleotide. However, these methods are distinct because they use wholly different reagents and wholly different method steps to produce wholly distinct products. Thus, Groups III and IV are patentably distinct. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Groups III and IV are related to Group V by virtue of the OxyR polynucleotide used in the methods since it encodes the polypeptide. However, the polypeptide is neither used nor produced in the claimed methods. Thus, Groups III and IV are patentably distinct from Group I. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

***Notice of Possible Rejoinder***

4. The Examiner notes that if product claims in Group I are found directed to an allowable product, then process claims in Groups III and IV, which are directed to processes of using the patentable product, previously withdrawn from consideration as a result of a restriction requirement, would now be rejoined pursuant to the procedures set forth in the Official Gazette notice dated March 26, 1996 (1184 O.G. 86; see also M.P.E.P. § 821.04, *In re Ochiai*, and *In re*

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Brouwer). Since process claims would be rejoined and fully examined for patentability under 37 C.F.R. § 1.104, Applicants are instructed to amend said claims as deemed necessary according to rejections made against the elected claims.

***Election***

5. A telephone call was made to Daniel Pereira on June 9, 2003 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 C.F.R. § 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(i).

***Conclusion***

6. A complete response to the instant Office action must include an election of invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathleen M Kerr whose telephone number is (703) 305-1229. The examiner can normally be reached on Monday through Friday, from 8:30am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathupura Achutamurthy can be reached on (703) 308-3804. The fax phone

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numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

KMK



June 9, 2003